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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/462,682	04/28/2000	DAVID J. FITZGERALD	015280-31010	5396

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TOWNSEND AND TOWNSEND AND CREW
TWO EMBARCADERO CENTER
8TH FLOOR
SAN FRANCISCO, CA 94111-3834

EXAMINER

PORTNER, VIRGINIA ALLEN

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 03/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	Application No. 09/462,682	Applicant(s) FITZGERALD, DAVID J.	
	Examiner Ginny Portner	Art Unit 1645	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED Nov. 16, 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The reply was filed after the date of filing a Notice of Appeal, but prior to the date of filing an appeal brief. The Notice of Appeal was filed on 16 November 2004. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
- (a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☒ They raise the issue of new matter (see NOTE below);
- (c) ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: see attachment. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
- The status of the claim(s) is (or will be) as follows:
- Claim(s) allowed: _____.
- Claim(s) objected to: 2, 7 and 8.
- Claim(s) rejected: 1-3, 7, 8, 12, 13 and 46-50.
- Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attachment.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____
13. ☐ Other: _____.

For at least the following reasons, the Amendment After Final submitted November 2004 has not been entered:

1. Claim 1 has been proposed to recite the phrase :

“a translocation domain comprising a polypeptide having an amino acid **subsequence** at least 95 % identical to the sequence of Pseudomonas exotoxin A (PE) (SEQ ID NO 2).

The term “subsequence” raises a new issue After Final, as none of the pending claims have previously recited this combination of claim limitations directed to a translocation domain that is a polypeptide with an embedded amino acid sequence that is a subsequence within the polypeptide domain that only shares 95% identity with SEQ ID NO 2. What the rest of the polypeptide outside the subsequence is, is not defined in the claims other than by biological function of the overall polypeptide that is a translocation domain. The recitation of the term “subsequence” raises an issue under 35 USC 112, first and second paragraphs as to what the complete translocation domain looks like with respect to the overall polypeptide structure, as only a “subsequence of the domain is proposed to share 95 % identity with SEQ Id No 2, and would comprise additional amino acids as the sequence that shares 95% identity is only a portion of the domain, as it is claimed to be a “subsequence” of the whole domain.

2. Claim 1 is also proposed to be amended to recite the phrase:

“(3) an epitope presenting domain having an amino acid sequence of between 5 and 350 amino acids in length consisting essentially of one cysteine to cysteine disulfide bonded loop of a pathogen wherein the loop encodes an epitope of the pathogen”.

Paragraph (3) defines a domain to contain 5 to 350 amino acids, but redefines the domain to “consisting essentially of one cysteine to cysteine disulfide bonded loop”. This is only

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two amino acids and not the minimum of 5 amino acids. Additionally, the loop encodes the epitope, but the loop comprises one cysteine to cysteine disulfide amino acid sequence. The proposed combination of claim limitations is not internally consistent with respect to the size and sequence of the epitope presenting domain and therefore would raise new issues After Final.

3. The newly proposed combination of claim limitations raises a new issue After Final and is therefore not entered.

Response to Arguments

4. Claims 1-3, 7-8, 12-13, 46-50 rejected under 35 U.S.C. 103(a) as being unpatentable over Wels et al and Pastan et al is traversed based upon the newly submitted combination of claim limitations not entered. Traversal directed to a combination of claim limitations not entered is not commensurate in scope with the pending claims and is therefore not convincing.

5. Claims 1, 46 and 47 rejected under 35 USC 112, first paragraph, written description is traversed based upon a combination of claim limitations not entered After Final. Applicant's assertion that only 3 amino acids may be changed in domain 2 based upon the proposed amendment directed 95% identity over the range of amino acids 280-344, has been fully considered but is not convincing because while 95% of the recited range is 3 amino acids, the independent claim has also been amended to define the recited range to be a subsequence of the polypeptide amino acid sequence. This combination of claim limitations has not been entered as it raises new issue After Final with respect to what the overall sequence of the polypeptide when only a subsequence portion is structurally defined and the rest of the polypeptide is only defined

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by function and not structure. Applicant's traversal is directed to a combination of claim limitations not entered and ^{is}~~are~~ therefore not commensurate in scope with the pending claims.

1. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (571) 272-0862. The examiner can normally be reached on M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vgp
March 15, 2005

L. J. Smith
Lynette Smith
Supervisor
Art Unit 1645
Patent and Trademark Office
U.S. Department of Commerce